

## REMARKS

The Office Action mailed January 30, 2004 has been received and the Examiner's comments carefully reviewed. Claims 1, 23, and 32 have been amended. Claims 33 and 34 have been added. No new subject matter has been added. Claims 12, 15, 16, 22 and 24 have been withdrawn from consideration pursuant to the restriction requirement of October 3, 2003. Claims 1-34 are currently pending. Applicants respectfully submit that the pending claims are in condition for allowance.

It is noted that Applicants submitted Supplemental Information Disclosure Statements on November 4, 2002 and February 5, 2003. Applicants respectfully request that the Examiner return a copy of the initialed 1449 Forms with the next communication.

### Rejections Under 35 U.S.C. §112

The Examiner rejected claim 23 under 35 U.S.C. §112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Applicants have amended claim 23 to correct the antecedent basis of a recited "stent." Applicants respectfully submit that claim 23 is now in condition for allowance.

### Rejections Under 35 U.S.C. §102

I. The Examiner rejected claims 1, 4 and 20 under 35 U.S.C. §102(e) as being anticipated by Dusbabek et al. (U.S. Patent 6,203,558). Applicants respectfully traverse this rejection, but have amended claim 1 to advance this application to allowance. Applicants reserve the right to pursue the original subject matter via a continuing application.

Dusbabek discloses a stent delivery system having a balloon 14 bonded to an outer member 24 and an inner member 26. The outer member 24 defines a lumen 28 through which fluid is communicated to expand the balloon 14, and in turn, expand a stent 18 mounted over the balloon 14. The Examiner indicated that Dusbabek discloses all the elements of claim 1. As a basis for this rejection, the Examiner has characterized the lumen

28 (i.e. the end of the outer member 24) as a spacer, and has characterized the balloon 14 as an outer tubular member.

Claim 1 recites a catheter system including an outer tubular member and an inner tubular member, the inner member being disposed within the outer member such that a fluid channel is defined between the inner and outer tubular members. The fluid channel has a length that extends a majority of the distance between first and second ends of the catheter system.

Applicants respectfully note that element 14 of Dusbabek is not an outer tubular member as recited in the overall context of claim 1. Element 14 of Dusbabek is a balloon 14 for expanding a stent. Nonetheless, Applicants have amended claim 1 to clarify that the fluid channel between the inner and outer tubular members has a length that extends a majority of a distance between the ends of the catheter system. Dusbabek does not disclose a fluid channel length as recited in claim 1. In contrast, the fluid channel between the balloon 14 and the inner member 26 of Dusbabek extends only a short distance adjacent to the distal end of the system, not a majority of the distance between the ends of the system.

With regards to claim 20, Dusbabek does not disclose a discharge opening located near a distal end of the balloon 14. Rather, the "discharge opening" location near element 28, as referred to by Examiner, is located near the proximal end of the balloon 14; not the distal end.

At least for these reasons, Applicants respectfully submit that independent claim 1, and dependent claims 4 and 20 are patentable.

II. The Examiner rejected claims 25, 28, 29 and 32 under 35 U.S.C. §102(e) as being anticipated by Fiedler (U.S. Patent 6,605,109). Applicants respectfully traverse this rejection.

Fiedler discloses a fluid actuated stent delivery system. The system includes a stent retaining sleeve member 36 slidably mounted to a secondary tube 26. Pressure seals 38, 40 provide a fluid-tight chamber 42 between the sleeve 36 and the secondary tube 26 such that pressurized fluids expelled from the distal end 44 of the secondary tube 26, which preferably occurs between seals 38 and 40, produces a desired retraction. Column 5, lines 5-10 and 17-23.

A. Claims 25, 28, and 29

Claim 25 recites a stent delivery system including an inner tubular member disposed within an outer tubular member defining a passageway therebetween. An admission port is in fluid communication with the passageway. The system further includes at least one fluid exchange aperture that delivers a media from said passageway to a patient's body lumen.

Fiedler does not disclose a system have a fluid exchange aperture that delivers media from a passageway, which is in turn, in fluid communication with an admission port. The construction of which the Examiner characterizes as an exchange aperture is a gap that exists when the sleeve 36 is retracted. This gap, however, is not constructed to deliver media from the "fluid-tight" pressure chamber 42, as required by claim 25. Rather, the fluid-tight pressure chamber 42 is sealed at both ends by pressure seals 38, 40 to prevent media from flowing out of the pressure chamber 42.

At least for this reason, Applicants respectfully submit that claim 25, and dependent claims 28 and 29 are patentable.

B. Claim 32

Claim 32 recites a stent delivery system including a catheter having a stent mounting location. The catheter further includes a retractable sheath. A fluid exchange passageway having fluid exchange openings that open to an exterior of the catheter are located near proximal and distal ends of the stent mounting location.

First, at least for similar reasons discussed above with regards to claim 25, Applicants respectfully submit that the gap to which the Examiner refers as an exchange opening is not part of a fluid passageway. Instead, the fluid passageway of Fiedler is provided by the secondary tube 26, which is in fluid communication with either a fluid-tight pressure chamber 42 or a sealed bellow 102. None of the secondary tube 26, the fluid-tight pressure chamber 42, or the sealed bellow 102 includes openings that open to an exterior of the catheter. Further, Fiedler does not teach or suggest that fluid or media is contained in the portion of the sleeve distal to the seal 38 (i.e. the portion of the sleeve 36 within which the stent is disposed).

Second, Fiedler does not disclose a fluid exchange opening located near the proximal end of the stent mounting location, as recited in claim 32.

At least for these reasons, Applicants respectfully submit that claim 32 is patentable.

#### Rejections Under 35 U.S.C. §103

I. The Examiner rejected claims 1-9, 17, 18, 19 and 23 under 35 U.S.C. §103(a) as being unpatentable over Fiedler (U.S. Patent 6,605,109) in view of Ponzi (U.S. Patent 5,964,757). The Examiner also rejected claims 1, 10-11, 13 and 14, 17, 18, 19 and 23 under 35 U.S.C. §103(a) as being unpatentable over Fiedler (U.S. Patent 6,605,109) in view of Divino Jr. et al. (U.S. Patent 6,676,900). Applicants respectfully traverse these rejections, however, Applicants have amended claim 1 to advance this application to allowance.

For each of these rejections, the Examiner relies upon Fiedler to teach inner and outer tubular members that define a fluid channel. As recited in claim 1, an admission port is in fluid communication with the fluid channel, and the length of the fluid channel extends a majority of a distance between first and second ends of the catheter system.

The "fluid channel" or pressurized chamber 42 of Fiedler that is in fluid communication with the secondary tube 26, is defined only between the seals 38, 40. The length of the pressure chamber 42 between the seals 38, 40 does not extend a majority of a distance between the first and second ends of the catheter system. Rather, the length of the pressure chamber 42 is at most, less than a majority of the distance between the ends of the system.

For each of these rejections, the Examiner also relies upon Fiedler to teach a spacer. As recited in claim 1, the spacer is disposed within the fluid channel for maintaining a spacing between inner and outer tubular members. Fiedler does not teach a spacer. The seals 38, 40 of Fiedler are simply seals, not spacers for maintaining a spacing between tubular member. Further, the seals 38, 40 are not disposed within a fluid channel; rather, the seals define and abut the ends of the "fluid-tight" pressure chamber 42.

At least for this reason, Applicants respectfully submit that independent claim 1, and dependent claims 2-11, 13, 14, 17, 18, 19, and 23 are patentable.

II. The Examiner rejected claim 21 under 35 U.S.C. §103(a) as being unpatentable over Dusbabek (U.S. Patent 6,203,558) in view of Matsuda et al. (U.S. Patent 5,840,066). The Examiner also rejected claims 26 and 27 under 35 U.S.C. §103(a) as being unpatentable over Fiedler (U.S. Patent 6,605,109) in view of Matsuda et al. (U.S. Patent 5,840,066); claim 30 under 35 U.S.C. §103(a) as being unpatentable over Fiedler (U.S. Patent 6,605,109) in view of Little (U.S. Patent 5,005,584); and claim 31 under 35 U.S.C. §103(a) as being unpatentable over Fiedler (U.S. Patent 6,605,109) in view of Bigus (U.S. Patent 6,629,992). Applicants respectfully traverse these rejections.

Claim 21 depends upon claim 1. Claims 26, 27, 30 and 31 depend upon claim 25. In view of the remarks regarding independent claims 1 and 25, further discussion regarding the independent patentability of dependent claims 21, 26, 27, 30 and 31 is believed to be unnecessary. Applicants submit that dependent claims 21, 26, 27, 30 and 31 are in condition for allowance.

#### New Claims 33-34

Claim 33 incorporates the subject matter of claims 1, 10 and 11. Claim 34 incorporates the subject matter of claims 1 and 14. Because new claims 33 and 34 are simply claims 11 and 14 rewritten in independent form, Applicants have below addressed the Examiner's rejections with regards to claims 11 and 14.

The Examiner rejected claims 11 and 14 under 35 U.S.C. §103(a) as being unpatentable over Fiedler (U.S. Patent 6,605,109) in view of Divino Jr. et al. (U.S. Patent 6,676,900). Applicants respectfully traverse this rejection.

A summary of Fiedler is discussed above. With regards to Divino, Divino discloses a system 10 having a housing portion 40 including a fluid return lumen 52. An oxygen-saturated fluid line 76 and a blood flow lumen 74 merge within the housing; the merged flow exits the fluid return lumen 52. The distal end of the oxygen-saturated fluid line 76 may be supported within the blood flow lumen 74 by wings 72.

Neither Fiedler nor Divion teaches a spacer traverses at least 10 percent of the fluid channel. In the particular rejection of original claims 11 and 14, the Examiner has overlooked this limitation, as neither the seal 38 of Fiedler nor the wing 72 of Divino traverses 10 percent of a fluid channel.

Further, the Examiner stated that it would have been obvious to substitute the seal 38 of Fiedler with the wings 72 taught by Divino. Applicants respectfully submit that this combination would render the device of Fiedler inoperable. Specifically, Fiedler relies upon the seals 38, 40 to provide a "fluid-tight" pressure chamber 42 to axially move the sleeve 36 and expose a stent. Incorporating the wings 72 of Fiedler would not provide the pressure chamber required to axially slide the sleeve 36, thereby rendering the device inoperable.

At least for these reasons, Applicants respectfully submit that claim 33 and 34 are patentable.

### SUMMARY

It is respectfully submitted that each of the presently pending claims (claims 1-34) is in condition for allowance and notification to that effect is requested. The Examiner is invited to contact Applicants' representative at the below-listed telephone number if it is believed that prosecution of this application may be assisted thereby.

Although certain arguments regarding patentability are set forth herein, there may be other arguments and reasons why the claimed invention is patentably distinct. Applicants reserve the right to raise these arguments in the future.

Respectfully submitted,



MERCHANT & GOULD P.C.  
P.O. Box 2903  
Minneapolis, Minnesota 55402-0903  
(612) 332-5300

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Karen A. Fitzsimmons  
Reg. No. 50,470  
KAF:cjm